

# **EXHIBIT P**

# BUTLER | SNOW

December 18, 2013

Andrew Faes  
Wagstaff & Cartmell LLP  
4740 Grand Avenue - Suite 300  
Kansas City, Missouri 64112

RE: *In re: Ethicon, Inc. MDL*

Dear Andrew:

Please accept this letter in response to your letter, dated November 25, 2013 requesting additional information about issues raised in my November 5, 2013 letter to Tom Cartmell.

First, you request confirmation of the bates range for the patient data binder. The bates range you provided is correct. This information is in Production 179 at ETH.MESH.10585029 – ETH.MESH.10585501. In addition, you request the custodial source and geographic location of the binder. As a preliminary matter, we note that there was an error in the transmittal letter. The correct source information is as follows<sup>1</sup>:

PRODUCTION 179 BATES RANGES		SOURCE	TITLE
START	END		
10585010	10585028	Consultant Paper Files	N/A
10585029	10585501	Quality Systems Central Files	N/A
10585502	10589323	Evita	N/A
10589324	10591877	Leslie, Irene	Assoc. Director

As previously communicated, this binder of documents was referenced in an email chain circa 2005 (ETH.MESH.05220458 - ETH.MESH.05220464), relating to a pallet of twelve cases of Medscand materials that were in the possession of Cooper Surgical around the time it purchased Medscand in or about 2005. It is our understanding that in November 2005, Cooper Surgical sent the pallet of twelve cases to Johnson & Johnson International. It is further our understanding that in February 2006, one of the cases, which contained clinical study information and included the binder, was shipped by Johnson and Johnson International from a warehouse in Sweden to Ethicon SARL in Neuchatel, Switzerland,

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<sup>1</sup> Evita is a German document management system. We have collected documents related to TVT from this system and are in the process of collecting documents regarding other pelvic mesh products as well.

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and Ethicon SARL sent the case to an offsite storage facility in Lausanne, Switzerland. (*See* Ex. A, ETH.MESH.10282067, Email from Helen Kahlson (distribution employee in Sweden) to Michel Willemin (distribution employee in Neuchatel) confirming shipment).

It is our understanding that the binder was stored in the Switzerland storage facility until a fire occurred on or around September 24, 2009. Immediately following the fire, defense counsel reached out to Plaintiffs in the New Jersey litigation to advise that the fire had occurred and provide the information that Ethicon had at that time. (*See* Ex. B, Letter from Kelly Crawford to Adam Slater and Beth Baldinger). After the fire occurred, we understand that any surviving documents, including the binder, were ultimately reassigned to other Ethicon SARL storage facilities in Switzerland. Carmel Lowe, the Records Manager at Neuchatel, facilitated locating the binder in Neuchatel's archives and sending it to us, at which point we reviewed and produced it.

Your letter also requests the production of any documentation regarding the binder of data, the case destroyed in the fire, and the fire itself. We have been unable to determine how or why the specific binder provided to you survived the fire. However, with this letter, we are producing an index of documents that we understand identifies documents that either survived or were destroyed in the September 24, 2009 fire. (*See* Ex. C, Index of Neuchatel documents post-fire).<sup>2</sup> We understand that Row 1336 corresponds to the patient data binder we produced. You will note that any other rows that correspond to clinical studies, e.g. Rows 960-965, indicate that the documents were destroyed in the September 24, 2009 fire. We have also previously produced CAPA090179 which was created after the fire in an effort ensure that all vital records are scanned and duplicated before being sent to offsite storage. We are continuing to investigate any insurance claims related to the fire.

Your letter further requests additional information on the 11 other cases of documents, seven of which purportedly contained product retains, and four of which purportedly contained lot documentation. As previously noted, our understanding is that those cases had been in a storage facility in Sweden until early 2006, at which time they were disposed of, as they no longer served any business purpose. We are producing an email from Michel Willemin (Neuchatel) asking Helen Kahlson (J&J International - Sweden) to ship clinical studies but not product retains. (*See* Ex. A). We have also confirmed that Helen Kahlson instructed another Sweden warehouse employee to dispose of the 11 cases. (*See* Ex. D, ETH.MESH.10282078, Email from Helen Kahlson to Birgitta Steen). However, we have not located a certificate of destruction.

For the seven cases that contained product retains, we understand that all of the product exemplars or product test retains would have been past the product's shelf life in 2006. Carmel Lowe, the current Records Manager at Neuchatel, confirmed that Laurent Soulier, a former Neuchatel quality manager, made the decision to have someone in Sweden ship the clinical studies, but not the other cases. Colin Yuill, the current Quality Manager in Neuchatel, confirmed that a product retain past its shelf life would not have been retained by Laurent Soulier

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<sup>2</sup> Exhibit C is attached hereto for reference. It will be incorporated into the general production.

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seeing as it no longer served a business purpose. As for the four boxes that purportedly contain lot documentation, we have not been able to ascertain exactly what lot documentation was in those boxes.

Finally, your letter requests an update on our investigation as to the existence of a Device Master Record (DMR) for the TVT Device. We have not located a Medscand DMR for the TVT Device, but we are continuing to ascertain whether a DMR was ever created during time frames when Medscand had responsibility for manufacture of the TVT product after the implementation of the 1997 Licensing Agreement and if so, whether those documents exist and are in the possession of Ethicon.

Sincerely,

BUTLER SNOW LLP

A handwritten signature in black ink, reading "Benjamin M. Watson". The signature is written in a cursive style with a large, stylized 'B' and 'W'.

Benjamin M. Watson

BMW:fsw

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